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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,157	12/20/2001	Richard E. Fulton	ARTM 1000-6US	1695

34263 7590 06/30/2003

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 06/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/027,157	FULTON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 21 April 2003.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-19,23,25,37-46,50 and 52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 2-17 and 37-45 is/are allowed.
- 6) Claim(s) 1,18,19,23,46 and 50 is/are rejected.
- 7) Claim(s) 25 and 52 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a)  The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8</u> . | 6) <input type="checkbox"/> Other: _____                                    |

***Claim Rejections - 35 USC § 102 & 35 USC § 103***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 19, 23, 46 and 50 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Haaga ('392).

Haaga discloses a biopsy system with a hemostatic insert and further discloses taking a tissue sample from a biopsy site; and positioning a bioabsorbable element at the biopsy site. See Column 4, lines 3-19; Column 6, lines 11-34; Column 7, lines 40-67; and Column 8, lines 1-9.

Even though Haaga does not disclose the testing of the sample and relocating the biopsy site by palpation or remote visualization, it would have been obvious to one of ordinary skill in the art at the time the invention was made to relocate the biopsy site after the test results necessitated the need to do so by utilizing the properties of the expandable bioabsorbable element. Since the bioabsorbable element consists of a different density than that of the surrounding tissue, the biopsy site would be easily

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relocated through palpation or remote visualization, including ultrasound or mammography.

4. Claims 1 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Haaga ('392).

Haaga, as discussed above, discloses a biopsy system with a hemostatic insert and further disclose a bioabsorbable element locatable at a soft target tissue site of a patient; the bioabsorbable element being of a material that is palpably harder than the surrounding tissue at the target site; and a bioabsorbable element configured for positioning at a biopsy site at the time of taking a tissue sample from the biopsy site.

See Column 4, lines 3-19; Column 6, lines 11-34; Column 7, lines 40-67; and Column 8, lines 1-9.

#### ***Allowable Subject Matter***

5. Claims 23, 25 and 52 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

6. The following is a statement of reasons for the indication of allowable subject matter: Claims 2-17 and 37-45 are allowable since no prior art could be found concerning or suggesting the bioabsorbable element having a longest dimension of at least about 0.5 cm when in the post-delivery state; and relocating the bioabsorbable element by following a bioabsorbable thread, the thread extends from the patient's skin to the bioabsorbable element.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (703) 308-3737 and group fax number is (703) 308-0758. The examiner can normally be reached on Monday-Friday, with second Fridays off.

  
BS  
June 24, 2003

  
MAX F. HINDENBURG  
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